Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Regulatory Directive

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Formulants Policy and Implementation Guidance Document

This Regulatory Directive outlines Health Canada's Pest Management Regulatory Agency (PMRA) policy on the regulation of formulants contained in pest control products (Part I). It also provides practical guidance to applicants and registrants on implementation of the Formulants Policy (Part II). The Formulants Policy applies to registration decisions in relation to formulants in manufacturing concentrates and registered end-use products, applications for research permits and in relation to the re-evaluation of products.

This document replaces Regulatory Directive DIR2004-01, *Formulants Program*. Revisions to the document pertain mainly to changes in the labelling of List 2 formulants as well as the addition of further guidance on the implementation of the Policy.

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6605C
Ottawa, Ontario
K1A 0K9

Internet: pmra_publications@hc-sc.gc.ca
www.pmra-arla.gc.ca
Information Service:
1 800 267-6315 or 613 736-3799
Facsimile: 613 736-3758

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Foreword

Health Canada's Pest Management Regulatory Agency (PMRA) is implementing a policy on the regulation of formulants. A formulant is any substance, other than an active ingredient, intentionally added to a pest control product. The policy is based on the approach followed by the United States Environmental Protection Agency (USEPA)[1] and represents another step leading towards harmonization of pesticide regulation. Formulants have been assigned to several lists. List 1 includes formulants of toxicological concern (as on current and previous USEPA Inert List 1[2,3,4]), those meeting criteria of the federal Toxic Substances Management Policy (TSMP) and those subject to the Montreal Protocol on Substances that Deplete the Ozone Layer. List 2 contains formulants considered to be potentially toxic. List 3 contains formulants that do not meet criteria for the other lists. List 4A formulants are of minimal toxicologic concern. List 4B contains formulants of minimal concern under specific conditions of use. As a starting point, most formulants have been categorized using the USEPA lists. Where the list number assigned for a particular formulant in Canada differs from that assigned by the USEPA, regulatory action as outlined in this Regulatory Directive is based on the PMRA list number. Formulants unique to products registered in Canada will be assigned to the various lists as information is received. For a consolidated listing of all formulants found in Canadian registered pest control products and categorized according to the five lists, refer to Regulatory Note REG2005-01, *PMRA List of Formulants*, or the latest version.

To update available information, statement of product specification forms (SPSFs) of control products are required to be submitted with each submission to register, to amend, to renew or to conduct research with a control product.

List 1 formulants have been virtually eliminated from pest control products. For the few remaining products containing List 1 formulants, safety data, which have been submitted to support the continued use of the particular List 1 formulants, are currently being reviewed.

Labelling will be required for formulation preservatives and for allergens known to cause anaphylactic-type reactions. The policy also sets forth acceptability criteria for dyes, colourants and fragrances as well as criteria for notifiable changes to product labels and formulations. New requirements established under this policy are being phased in over a three-year period, which began 9 January 2005.

Part II of this document provides guidance to applicants and registrants on how to comply with the Formulants Policy and the resulting new requirements.

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1 United States 52 Federal Register Notice 13305, 22 April 1987

2 Ibid

3 United States Federal Register, 24 June 1998, pp. 34384–34290

4 www.epa.gov/opprd001/inerts/lists.html [Inert (other) Pesticide Ingredients in Pesticide Products - Categorized List of Inert (other) Pesticide Ingredients]

Table of Contents

PART I Formulants Policy 1

1.0 Introduction 1
- 1.1 Key Elements of the PMRA Formulants Policy 1
- 1.2 Definitions 2
- 1.3 Effective Date 3

2.0 Legal Authority and Related Policies 3
- 2.1 Formulants Determined to Be of Concern According to Other Federal Legislation/Policies (including the TSMP) 3
- 2.2 Formulants Subject to the Directives of the Montreal Protocol 4

3.0 Categorization of Formulants Currently in Use in Canada 4
- 3.1 List 1—Formulants of Toxicological Concern 4
- 3.2 List 2—Potentially Toxic Formulants with a High Priority for Testing 5
- 3.3 List 3—Formulants That Do Not Meet the Criteria of Lists 1, 2, 4A and 4B 6
- 3.4 List 4A—Formulants of Minimal Toxicological Concern 6
- 3.5 List 4B—Formulants of Minimal Concern under Specific Conditions of Use 6
- 3.6 Formulants Unique to Canada 7
- 3.7 Formulants No Longer Used 7

4.0 Regulatory Actions on Formulants Currently in Use in Canada 7
- 4.1 Statement of Product Specification Form Update 7
- 4.2 Conversion of Guarantee Statement from Minimum to Nominal 8
- 4.3 Regulatory Action on Pest Control Products That Contain List 1 Formulants 8
- 4.4 Regulatory Action on Pest Control Products That Contain List 2 Formulants 12
- 4.5 Regulatory Action on Pest Control Products That Contain List 3 Formulants 14
- 4.6 Regulatory Action on Pest Control Products That Contain List 4A and List 4B Formulants 14
- 4.7 Regulatory Action on Formulants Unique to Canada 14
- 4.8 Regulatory Action for Formulants in Products Containing Active Ingredients under Re-evaluation 15
- 4.9 Regulatory Action on Pest Control Products That Contain Polymers as Formulants 15
- 4.10 Regulatory Action on Pest Control Products That Contain Proprietary Formulants or Mixtures 16
- 4.11 Research Permits 17
- 4.12 Adjuvants Added to Pest Control Products Prior to Application (tank-mix adjuvants) 17
- 4.13 Labelling Requirements for Formulation Preservatives 17
- 4.14 Labelling Requirements for Formulants That Are Allergens Known to Cause Anaphylactic Type Reactions 18
- 4.15 Acceptability Criteria for Dyes and Colourants, Fragrances or Oils Used as Formulants 19
- 4.16 Changes Concerning Formulants Allowable by Notification 20

5.0 Regulatory Actions for New Formulants in Canadian Pest Control Products 23

PART II Guidance on How to Comply with the Formulants Policy 25

1.0 Introduction 25

2.0 PMRA List of Formulants 25

3.0 Formulant Reclassification 26

4.0 Implementation Approach 26
4.1 Labelling Disclosure Deadlines for Allergens and Formulation Preservatives 26

5.0 Requirements Already in Effect 26
5.1 Formulant Information 27
5.2 New Formulants 27
5.3 List 1 Formulant Label Disclosure 28

6.0 New Requirements 28
6.1 Statement of Product Specification Forms (SPSFs) 28
6.2 List 2 Formulants 29
6.2.1 Reclassification of List 2 Formulants 29
6.3 Formulation Preservatives 30
6.3.1 Formulation Preservative Disclosure on the SPSF and Label 30
6.3.2 Label and SPSF Amendment Submission Timelines 31
6.3.3 Registration of Preservatives 33
6.4 Allergens 34
6.4.1 Allergen Label Disclosure 34
6.4.2 Label Amendment Submission Timelines 34
6.5 Dyes and Fragrances 35
6.6 Multiple Formulations Under the Same Registration Number 36
6.6.1 Acceptability Criteria 37
6.6.2 How to Represent Multiple Formulations on the SPSF 37
6.6.3 Label Disclosure for Products with Multiple Formulations 39
6.6.4 Registered Products Containing Multiple Formulations 39

7.0 Notifiable Changes 40

List of Abbreviations 41

Appendix I Common Errors Made When Completing SPSF 43

Appendix II Summary of Time Frames for New Requirements 45

PART I Formulants Policy

1.0 Introduction

This policy outlines how formulants in pest control products are regulated. The Pest Management Regulatory Agency (PMRA) is taking action to ensure that information on formulations and identification of formulants are accurate and meet current standards. The Agency requires either elimination of certain toxic formulants from products or appropriate data to support the safety of their continued use. The PMRA also encourages the use of the least toxic formulants available that are appropriate to the formulation. As per current policy, in addition to data/information required for an individual formulant, data (e.g., acute toxicity, efficacy, etc.) may also be required on the end-use formulation containing the formulant for applications submitted to register new products or for product amendments.

The high degree of concordance between formulants used in Canadian pest control products and those used in products in the United States has allowed the Canadian policy to be based on and to be directed towards harmonization with the United States Environmental Protection Agency (USEPA) policy on inerts (also referred to as other ingredients).

By implementing this directive, the PMRA will have a formulants policy that is similar to the USEPA policy. Further steps towards harmonization will take place under the North American Free Trade Agreement Technical Working Group on Pesticides. The PMRA recognizes that a step-wise process is required for the implementation of the formulants policy. To optimize efficiency and reduce resource requirements, the Agency will use USEPA reviews for decisions on Canadian formulants whenever possible.

1.1 Key Elements of the PMRA Formulants Policy

This Formulants Policy:

- will lead to increased harmonization of Canadian regulatory approaches for formulants with those of the USEPA by adopting and building on their lists of inerts (formulants);
- requires applicants and registrants to submit updated statement of product specification forms (SPSFs) with all submissions to register, to amend, to renew or to conduct research with a control product, with identification of individual formulants by Chemical Abstracts Service (CAS) Registry Numbers, where one exists;
- applies the directives of the Toxic Substances Management Policy (TSMP) and the Montreal Protocol to formulants that meet the criteria of these policies;

- requires data and label identification of formulants and, in selected cases, removal or substitution of formulants that have potential or identified toxicological concerns;

- requires label identification of active ingredients that are present in the end-use formulation as formulation preservatives;

- sets acceptability criteria for formulants that are dyes, fragrances or oils; and

- requires label identification of formulants that are common allergens known to be associated with anaphylactic reactions.

1.2 Definitions

Active ingredient: the ingredient(s) of a pest control product to which the effects of the product are attributed, including any synergist, not including a solvent, diluent, emulsifier or ingredient that by itself is not primarily responsible for the effect of the product.

Adjuvant: a formulant used by the end user for in-tank mixing with a control product. Adjuvants whose intended use is to directly improve the efficacy or enhance the biological performance of the control product are registered under the authority of the *Pest Control Products Act* (PCPA) and Regulations.

Formulant: any substance or group of substances other than the active ingredient that is intentionally added to a pest control product to improve its physical characteristics (e.g., sprayability, solubility, spreadability and stability).

Formulant mixture: a formulant composed of more than one substance.

Inert (other) ingredient: the USEPA terminology equivalent to the term formulant.

New formulant: any formulant that is not in a currently Canadian registered pest control product and is not on the USEPA inerts lists.

New use of a formulant: the formulant has not been identified for that purpose in an approved pesticide formulation in Canada or the United States.

Pest control product: any product, device, organism, substance or thing that is manufactured, represented, sold or used as a means for directly or indirectly controlling, preventing, destroying, mitigating, attracting or repelling any pest and includes the following:

1. any compound or substance that enhances or modifies or is intended to enhance or modify the physical or chemical characteristics of a control product to which it is added; and

2. any active ingredient used for the manufacture of a control product.

Reactant: a component formulated into a pesticide formulation that reacts chemically with an active ingredient to modify its form, e.g., a reactant added to a formulation containing an acid form of an active ingredient to make a corresponding amine form of the same active ingredient. Reactants are generally completely used up in the chemical reaction with the active ingredient. Therefore, they are not normally considered to be formulants and are outside the scope of this policy. Such compounds must be identified as reactants on SPSFs.

Safener: a formulant in some herbicidal pest control products that mitigates the effects of the product on specific economically important crops. Safeners are biologically active; therefore, they are subject to the same data requirements as for an active ingredient.

1.3 Effective Date

New requirements established in the Formulants Policy are being phased in over a three-year period that began 9 January 2005. The implications of the Policy on submissions in process and applications received within the pre-implementation period are covered in Part II of this document.

2.0 Legal Authority and Related Policies

The PMRA regulates all pest control products that are used, sold or imported into Canada. The Canadian federal legislative authority for the regulation of pest control products, including their formulants, is derived from the PCPA and Regulations as well as the *Food and Drugs Act* and Regulations.

2.1 Formulants Determined to Be of Concern According to Other Federal Legislation/Policies (including the TSMP)

Appropriate regulatory action may need to be undertaken in order to manage/eliminate the use of formulants identified as being of concern with respect to human health or the environment under other federal legislation or policies. For example, the PMRA is applying its Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, to formulants. The TSMP was developed to provide a common approach for developing and implementing measures to minimize or reduce the use and release of substances added to Schedule 1 of the *Canadian Environmental Protection Act*, 1999 (CEPA 1999). The PMRA is coordinating these activities for the pesticide sector. Formulants that meet TSMP Track 1 criteria are included in List 1.

2.2 Formulants Subject to the Directives of the Montreal Protocol

In 1980, the Canadian federal government established regulations under the *Environmental Contaminants Act* to prohibit the use of chlorofluorocarbons (CFCs) in aerosols for certain personal products. In 1987, Canada became a signatory to the Montreal Protocol, which sets out a schedule to control ozone-depleting substances.

In keeping with the goals of the Protocol, as of April 1989, CFCs -11, -12, -113, -114 and -115 were no longer permitted for use in pest control products (see Regulatory Directive DIR93-11, *Chlorofluorocarbons in Pesticide Products*).

A subsequent amendment to the Protocol incorporated other ozone-depleting chemicals, including CFCs, carbon tetrachloride, 1,1,1-trichloroethane (TCE), hydrochlorofluorocarbons (HCFCs) and methyl bromide. The PMRA no longer supports the use of ozone-depleting chemicals as formulants, and no new registrations or renewals will be issued for products containing them. Registrants with products that currently contain these chemicals as formulants are required to reformulate or discontinue the product. A list of possible alternatives or substitutes is found at Environment Canada's website at www.ec.gc.ca/ozone.

3.0 Categorization of Formulants Currently in Use in Canada

Existing formulants contained in registered pest control products in Canada have been assigned to one of the following five lists ranked in descending order of concern to establish priorities for regulatory activities. The regulatory actions proposed for formulants on each list are described in detail in Section 4. For a complete listing of formulants found in Canadian registered pest control products and their associated list numbers, refer to Regulatory Note REG2005-01, *PMRA List of Formulants*, or the latest version. The most recent USEPA inerts lists are available on the USEPA website at www.epa.gov/opprd001/inerts/lists.html.

3.1 List 1—Formulants of Toxicological Concern

List 1 consists of formulants identified as being of significant concern with respect to their potential adverse effects on health and the environment. As a starting basis, List 1 includes all formulants presently or previously listed on the USEPA List 1 and any additional formulant in Canadian products that meet any criterion for any one of the following categories.

Carcinogenicity

- a rating as a human carcinogen or probable or possible human carcinogen by the International Agency for Research on Cancer (rating 1, 2A or 2B);
- characterized by the United States National Toxicology Program as an animal carcinogen in at least one species and one sex; and/or
- regulated by a Canadian or American federal agency as a carcinogen.

Neurotoxicity and Chronic Effects

- identified in the American publication *Occupational Diseases, A Guide to Their Recognition*[5] as causing neurotoxicological and chronic effects in the workplace environment;
- regulated by a Canadian or American federal agency as a neurotoxin; and/or
- peer-reviewed study, included in the Toxicology Data Bank of the United States National Library of Medicine, reporting neurotoxic or chronic effects.

Adverse Reproductive Effects

- regulated by a Canadian or American federal agency as causing adverse reproductive effects; and/or
- peer-reviewed study, included in the Toxicology Data Bank of the United States National Library of Medicine, reporting adverse reproductive effects.

Ecological Effects

- a lethal concentration 50% (LC_{50}) of less than one part per million (this USEPA criterion refers to aquatic toxicity, i.e., potential for persistence and an aquatic $LC_{50} < 1$ mg/L); and/or
- a potential for bioaccumulation (the PMRA, like the USEPA, will consider persistence as a factor in this criterion, i.e., potential for persistence and bioaccumulation).

Formulants That Meet the Track 1 Criteria of the TSMP

See Section 2.1 above.

Formulants That Meet the Criteria of the Montreal Protocol

See Section 2.2 above.

The goal of the PMRA is to have List 1 formulants removed from products or supported with data to demonstrate no unacceptable risk. Registrants with List 1 formulants in their product are subject to the regulatory actions outlined for List 1 in Section 4.3.

3.2 List 2—Potentially Toxic Formulants with a High Priority for Testing

List 2 contains formulants that are considered to be potentially toxic, based on either structural similarity to List 1 formulants or data suggestive of toxicity. Most of the chemicals on the USEPA List 2 were designated for testing through the United States National Toxicology Program, the USEPA Office of Toxic Substances and other American regulatory or government bodies. Reassessment of List 2 chemicals is underway in the United States. Formulants in Canadian products that are subject to reassessment and possible data call-in by the USEPA will also be subject to appropriate

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5 National Institute for Occupational Safety and Health. 1977. *Occupational Diseases, A Guide to Their Recognition*. United States Department of Health, Education and Welfare; Public Health Service; Center for Disease Control; National Institute for Occupational Safety and Health. Publication Number No. 77-181.

regulatory action in Canada. Regulatory action for List 2 formulants is described in Section 4.4.

3.3 List 3—Formulants That Do Not Meet the Criteria of Lists 1, 2, 4A and 4B

List 3 contains the formulants in use in registered pest control products that do not meet the criteria of any of the other lists. Regulatory action for List 3 formulants is described in Section 4.5.

3.4 List 4A—Formulants of Minimal Toxicological Concern

List 4A contains formulants that appear on the United States Minimum Risk Inerts List that are generally regarded to be of minimal toxicological concern as well as substances commonly consumed as foods.[6,7] Based on their known properties, formulants on List 4A are considered acceptable in pest control products for both food and non-food uses with no further data necessary for the formulant alone. Regulatory action planned for List 4A formulants is described in Section 4.6.

3.5 List 4B—Formulants of Minimal Concern under Specific Conditions of Use

List 4B includes formulants, some of which may be toxic, but for which there are sufficient data to reasonably conclude that the specific use pattern of the pest control product (as listed in the United States Code of Federal Regulations, 40 CFR Protection of Environment, Subpart D, Sections 180.910, 180.920 and 180.930) will not adversely affect public health or the environment. List 4B includes formulants that meet the following criteria:

- they were approved by the United States Food and Drug Administration (USFDA) or under the Canadian *Food and Drugs Act* and Regulations for use as direct food or drug additives—concentration restrictions are applicable;
- they are polymers considered not to pose an unacceptable risk owing to such characteristics as size and lack of absorbability (Section 4.9); or
- they were evaluated within an approved use pattern and determined to be of minimal risk for that use only.

Regulatory action proposed for List 4B formulants is described in Section 4.6. If the use pattern or proposed use pattern of a 4B formulant is beyond that approved by the USEPA, the PMRA will require an independent review.

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6 United States Federal Register Document 94-23890, 28 September 1994

7 United States FR December 4, 1998, pp. 66 999–67 001

3.6 Formulants Unique to Canada

Formulants are unique to Canada if they:

1. do not appear on the USEPA lists; or
2. are proprietary formulants or mixtures where individual components require identification and placement on the appropriate list.

Regulatory action proposed for formulants unique to Canada is described in Section 4.7.

3.7 Formulants No Longer Used

Previously listed chemicals that are determined to no longer be used in pest control products will be removed from the lists of formulants[8]. If a registrant wishes to reactivate their use, these formulants will be considered "new" and will be subject to the appropriate requirements in order for the PMRA to determine that the use would not pose an unacceptable risk to human health or the environment.

4.0 Regulatory Actions on Formulants Currently in Use in Canada

Irrespective of the initial placement of a formulant on a specific list, if information becomes available to indicate a significant concern, the formulant is immediately subject to regulatory action that may include removal, substitution or data call-in to allow a risk assessment.

4.1 Statement of Product Specification Form Update

To ensure that information on formulations and identification of formulants is accurate and meets current standards, the Agency requires registrants to provide an updated SPSF for each submission to register, to amend, to renew or to conduct research with a control product or as outlined in the following sections, using a new SPSF (available electronically on the PMRA's website at www.pmra-arla.gc.ca). This requirement became effective on 5 January 2005. The information on the new SPSFs must:

1. accurately represent the product currently being formulated, including alternative formulations where acceptable; and

2. include all relevant information for each product component, supplier(s) name and address, percent weight per weight, certified limits, CAS number, formulant's list number and its purpose in the formulation.

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8 Consistent with United States 52 Federal Register Notice 13305, 22 April 1987

If registrants are already aware that changes have been made to their product formulations that are not reflected on the SPSF currently on file with the Agency, a formal application for amendment should be submitted along with the updated SPSF, appropriate data and fees.

4.2 Conversion of Guarantee Statement from Minimum to Nominal

To harmonize with the USEPA, the Agency is working with registrants to convert guarantees from minimum to nominal values. Although the focus of this policy is to update information on formulations and to eliminate certain formulants from products, it also provides opportunity for the simultaneous conversion of product specifications from minimum to nominal values.

If the information to make the conversion from minimum to nominal is not immediately available, the new SPSF for formulant policy purposes should be submitted with a minimum guarantee.

If the conversion to nominal results in a change in the guarantee statement, an application for label amendment, new draft labels showing the nominal guarantee and the application fee will be required if this activity is occurring simultaneously with the submission of an updated SPSF. Please note that conversion of guarantee statements from minimum to nominal for end-use products and manufacturing concentrates can only be accommodated at registration renewal if the source of the technical grade active ingredient is registered in nominal. Conversion of guarantee statements from minimum to nominal for technical grade active ingredients cannot be done at registration renewal and requires a separate application for product amendment.

Requirements and time frames for submission of updated specification forms, label amendments and data are described in detail within each of the following sections.

4.3 Regulatory Action on Pest Control Products That Contain List 1 Formulants

Since 1990, it has been the practice, on receipt of an application to amend a formulation or register a new formulation, to ask the applicant to substitute or remove formulants that were categorized as List 1 or List 2 on the USEPA List of Inert Ingredients (memorandum to Crop Protection Institute of Canada and Canadian Manufacturers of Chemical Specialties Association, 7 August 1990). In the case of List 1 formulants, label disclosure requirements were imposed where no suitable substitute could be found, as recommended in the Canadian Pesticide Registration Review (December 1990, p. 15). Consistent with the intent to progress towards harmonization with the USEPA Inerts Policy, the PMRA undertook an initiative to remove all List 1 formulants from pest control products in September 2001. Registrants of products containing List 1 formulants were given the three following options:

- immediate voluntary discontinuation of the product registration; OR
- substitution/removal of the List 1 formulant and interim disclosure labelling (with an application to amend the product formulation to be submitted by 31 December 2002); OR
- supporting the continued use of the List 1 formulant and interim disclosure labelling (with submission of safety data by 31 December 2002).

Failure to select and act upon one of the options resulted in cancellation of product registration.

List 1 formulants have been eliminated from almost all pest control products. For the few remaining products containing List 1 formulants, safety data, which have been submitted to support the continued use of the particular List 1 formulants, are currently being reviewed. As formulants are reclassified from other lists to List 1, products containing them will be dealt with in the same manner and within the same time frames, as outlined hereafter:

(a) Options for Registered Products with Future List 1 Formulants (except those subject to the Montreal Protocol)

When a formulant is reclassified to List 1, registrants of products containing that formulant will be subject to the following options within the timelines given, which are set from the date of notification of reclassification.

(i) Immediate Voluntary Discontinuation of a Product Containing the List 1 Formulant

Registrants may opt to voluntarily discontinue the product containing a List 1 formulant. Registrants must notify the PMRA if they choose to discontinue the product within four months of the date of notification of reclassification, and no further sale by the registrant will be allowed.

(ii) Retain the Product but Substitute for the List 1 Formulant

Registrants selecting this option have the responsibility to submit information demonstrating that the formulant used for substitution has no unacceptable health or environmental risks and that the product is still efficacious with the new formulant. Within 16 months of notification of reclassification, registrants must submit an application to amend their registered product.

Immediate substitution: Registrants may have sufficient information to apply immediately to amend the formulation of the product containing a List 1 formulant by the removal of the List 1 formulant and substitution with a formulant from other than List 1 and preferably not List 2. At the

time of application to amend the formulation, the registrant is expected to immediately cease manufacturing the product containing the List 1 formulant. Four months after notification of reclassification, any remaining old product containing the List 1 formulant not already in the channels of trade is subject to the disclosure labelling requirement as described in Section 4.3(b). Where a List 2 formulant is substituted, Section 4.4 applies.

Substitution with disclosure labelling: It is recognized that formulation changes may require new developmental work to verify the safety and efficacy of the amended end-use product. The registrant will be required to label the existing product not already in the channels of trade to indicate that it contains a List 1 formulant until application to amend the formulation is approved. Formulations with List 1 formulants will not be permitted to be sold by registrants or retailers after 28 months of notification of reclassification (except as according to (iii) below).

In view of the fact that a certain amount of the work on many new formulations (e.g., to generate efficacy data) must be carried out in the field, a use-season will be allowed for such work. Application for amendment with the required data must be received by the PMRA within 16 months of notification of reclassification or the registration will be cancelled, and all sale/import and use of the product will end.

(iii) Data Submission to Support the Use of the List 1 Formulant

Registrants may submit data to verify the safety of a product containing a List 1 formulant within 16 months of notification of reclassification, or the registration of the product will be cancelled. The data may be specific to the formulant or conducted with the formulation. (Submission of data on the formulation only would not allow an independent assessment of the formulant itself and thus would only support the particular product formulation.) Such data must be sufficiently comprehensive to allow the PMRA to conduct a complete risk assessment to determine that there are no unacceptable risks to health and the environment. Dependent on the use pattern to be supported, the data requirements may be as extensive as those for the active ingredient or may be tailored to the specific use scenario. Formulations with List 1 formulants will not be permitted to be sold after 28 months of notification of reclassification unless supported by an acceptable risk assessment.

(b) Disclosure of List 1 Formulants on Product Labels

Label disclosure is required for all products containing a List 1 formulant. Label disclosure changes may be carried out by notification and will apply to products in the hands of the registrants. Labels may be printed or overstickered. The following statement must appear within four months of notification of reclassification on the labels of any product containing a List 1 formulant that continues to be available as described above.

> "This product contains the toxic formulant (*insert name of chemical*) at (*insert percent weight/weight*) %."

This statement must be placed on the label in proximity to, on the same panel as, and in a type and font size comparable to, the guarantee statement.

(c) New Products with a List 1 Formulant

Applications submitted to register new products or to amend existing products containing List 1 formulants will not be accepted, unless information or data to specifically support the safety of the product containing the List 1 formulant accompanies the application.

(d) Regulatory Action on Pest Control Products That Contain Formulants Subject to the Montreal Protocol

The production of ozone-depleting chemicals is being phased out in accordance with the provisions of the Montreal Protocol. As this process continues, registrants with products currently containing ozone-depleting chemicals will be required to discontinue or reformulate them.

(i) Disclosure of Ozone-depleting Formulants

Until phased out, all products containing ozone-depleting chemicals governed by the Montreal Protocol must be labelled with the following statement if they are sold or distributed in Canada.

> "WARNING: This product contains (*insert name of chemical*), which harms public health and the environment by destroying the ozone in the upper atmosphere."

This statement must be placed on the label in proximity to, on the same panel as, and in a type and font size comparable to, the guarantee statement.

4.4 Regulatory Action on Pest Control Products That Contain List 2 Formulants

As previously noted in Section 3.2, List 2 formulants may have structural similarity to List 1 chemicals and are considered to be potentially toxic. Accordingly, the PMRA will be working with the USEPA to gather and review information on potential adverse effects of formulants on the USEPA Inert List 2, and to determine the necessary course of action for these formulants. **Should a List 2 formulant be found to meet List 1 criteria, it will be subject to the options and time frames as outlined in Section 4.3(a).**

The PMRA will be reassessing List 2 formulants and, where possible, will be coordinating reassessment activities with those of the USEPA, where the same formulant is being reassessed as part of the USEPA's reassessment of List 2 inert ingredients. Registrants with List 2 formulants in their products are strongly encouraged to consider amending formulations by substituting more acceptable alternatives such as those on Lists 3, 4A and 4B (if the use scenario applies) or submitting data/information to support the continued use of List 2 formulants. Registrants have the responsibility to submit information demonstrating that the List 2 formulant they wish to continue to use, or the formulant proposed for substitution, poses no unacceptable health or environmental risks, and that the product is still efficacious with the new formulant.

(a) Options for Registered Products with List 2 Formulants

The reassessment process will define the time frames for final resolution of List 2 formulants. As part of the reassessment process, there may be data call-ins for certain List 2 formulants. For the List 2 formulants subject to data call-in, registrants have the following options:

(i) Demonstrate the Absence of the List 2 Formulant

Registrants may opt to provide evidence that a List 2 formulant is no longer contained in the formulation. If there have been changes to the product formulation that are not reflected on the SPSF currently in the product register, registrants should apply for an amendment with appropriate data and fees. All formulants must be identified by CAS number where one exists. When formulants are mixtures, registrants should follow the directions described in Section 4.10 to ensure that the mixture does not contain List 2 formulants. If the information for changing to a nominal guarantee is readily available, this should also be submitted with the updated SPSF.

(ii) Voluntary Discontinuation of the Formulation with the List 2 Formulant

Registrants may opt to voluntarily discontinue the product. Registrants should notify the PMRA according to the provisions of the data call-in notice if they choose to discontinue the product. Reinstatement of these discontinued products will not be permitted without supporting data.

(iii) Amendment of the Formulation to Remove or Substitute the List 2 Formulant

Registrants may choose to make an application (with supporting data as required) to remove or substitute for a List 2 formulant that is subject to or pending data call-in. Preferably, any substitution should be with a formulant from List 3, 4A or 4B (if the use conditions apply). Registrants have the responsibility to provide any necessary information to demonstrate that the formulant used for substitution poses no unacceptable health or environmental risks and that the product is still efficacious with the new formulant.

(iv) Data Submission to Support the Use of the List 2 Formulant

Registrants have the option of supplying data to support safety in the use of the product containing the List 2 formulant subject to the data call-in. The data may be specific to the formulant or conducted with the formulation. Such data must be sufficiently comprehensive to allow the PMRA to conduct a risk assessment to determine that there are no unacceptable risks to health and the environment. Dependent on the use pattern to be supported, the data requirements may be as extensive as those for the active ingredient or may be tailored to the specific use scenario.

(b) New Products with List 2 Formulants

As of the date of the data call-in, applications submitted to register new products or to amend existing products containing List 2 formulants subject to the announced data call-in will not be accepted without supporting data.

New products with List 2 formulants not yet subject to data call-in will continue to be accepted; however, registrants should be aware that reassessment and possible data call-in are pending for all of the List 2 formulants. It is recommended that registrants plan early and make necessary formulation changes to minimize or avoid potential regulatory action.

4.5 Regulatory Action on Pest Control Products That Contain List 3 Formulants

The USEPA List 3 formulants have been subjected to a quantitative structure activity relationship (Q-SAR) analysis for structural alerts and do not have information available to demonstrate they meet the criteria of any of the other lists.

Registrants should be aware that as additional data become available, formulants on List 3 may meet the criteria of List 1 or List 2 and will be subject to the requirements described for lists 1 and 2, including the submission of data to support continued or new use. In the future, formulants remaining on List 3 will be subject to reassessment and possible data call-in to complete their database once the issues associated with the lists 1 and 2 formulants are approaching resolution. Registrants will be informed of the timing for the data call-in as work is completed on the higher priority, List 1 and List 2 formulants. If new information comes to light on any List 3 formulant that raises concern, the formulant will immediately be subject to the appropriate data requirement to support continued use.

4.6 Regulatory Action on Pest Control Products That Contain List 4A and List 4B Formulants

List 4A contains formulants that appear on the United States Minimum Risk Inerts List that are generally regarded to be of minimal toxicological concern as well as substances commonly consumed as foods. Based on their known properties, formulants on List 4A are considered acceptable in pest control products for both food and non-food uses with no further data necessary for the formulant alone. When a formulant is on List 4A, no further regulatory action is anticipated.

List 4B includes formulants, some of which may be toxic, but for which there are sufficient data to reasonably conclude that the specific use pattern of the pest control product (as listed in the United States Code of Federal Regulations, 40 CFR Protection of Environment, Subpart D, Sections 180.910, 180.920, and 180.930) will not adversely affect public health and the environment. When a formulant reaches List 4B, no further regulatory action is anticipated unless the use pattern for which it is being considered is beyond that approved, in which case the PMRA will require an independent review.

4.7 Regulatory Action on Formulants Unique to Canada

A number of formulants in Canadian products appear to be unique to Canada, as they do not appear on the USEPA lists or are proprietary mixtures whose individual components may or may not be on the USEPA lists.

As per current practice, all new submissions submitted to register or amend products will continue to require identification of all formulant components prior to review of the submission. It is the responsibility of the applicant to ensure that the identity of components in formulant mixtures be supplied to the PMRA. Applicants can request that

formulant manufacturers submit proprietary information to the PMRA Formulant Section under separate cover to support review of the submission as described in Section 4.10. Once all the components of a formulant mixture are identified, the formulant mixture will be assigned a list categorization number and be subject to the regulatory action and requirements for that list. The list number for a mixture is based on the components, i.e., the list number would be the one representing the highest level of concern. The order for formulants of most concern to least concern is 1, 2, 3, 4B, 4A. For example, if a mixture contained components from List 2, 3 and 4A, the mixture would be categorized to List 2. Formulants or formulant components that do not appear on a current PMRA or USEPA list will be subject to the appropriate data/information requirements to support continued use of existing products or any applications for new products.

4.8 Regulatory Action for Formulants in Products Containing Active Ingredients under Re-evaluation

As a part of the re-evaluation of technical grade active ingredients and their end-use products, registrants have been informed of the proposed direction the Agency will be taking with formulants. Registrants have been advised to take this into consideration when determining the course of action for their products under re-evaluation.

The regulatory requirement for individual formulants will be handled according to the outline in this Regulatory Directive and separately from the re-evaluation of technical grade active ingredients and end-use products.

4.9 Regulatory Action on Pest Control Products That Contain Polymers as Formulants

In the United States, certain polymers are exempt from data requirements when used as formulants in a pest control product formulation. Canada has adopted the same approach, and these polymers will be exempted from data requirements if they:

1. conform with the international definition of a polymer as adopted by the Organisation for Economic Co-operation and Development (OECD) in May 1993 (*Polymer Exemption Guidance Manual*, USEPA 744-B-97-001, 1997, p. 3); and

2. are eligible for use as an inert ingredient according to the USEPA requirements.

The terminology adopted and the USEPA policy regarding polymers is available on the Internet at www.epa.gov/opptintr/newchems/pubs/polyguid.pdf.

Formulants claiming polymer status that do not conform with the accepted international definition of a polymer described above will be subject to data requirements.

4.10 Regulatory Action on Pest Control Products That Contain Proprietary Formulants or Mixtures

Some formulants are claimed to be proprietary trade secrets, and the manufacturer may not wish to disclose the constituents of such formulants to a registrant or formulator. It is the responsibility of the registrant to arrange for the manufacturer of a proprietary formulant or mixture to disclose the composition of the proprietary formulant or mixture directly to the PMRA Formulants Section. The constituents of a proprietary formulant or mixture are subject to the provisions of the policy on formulants.

The fact that applicants use a proprietary formulant ingredient or mixture whose composition is not known to them does not remove their responsibility for maintaining the composition of each of those formulants within its certified limits and assuring that the composition of the proprietary formulant or mixture will not change over time. The PMRA believes that a contractual arrangement between a formulator and supplier or manufacturer is the best way to ensure that the formulator can rely on the composition of the material received. Registrants or formulant manufacturers are responsible for notifying the PMRA when the composition of a formulant mixture used in a pest control product is altered.

(a) Registered Products

If a product with an existing registration contains a formulant of toxicological concern comprising part of a proprietary formulant or mixture, the PMRA will notify the registrant that the formulant contains a proprietary formulant or mixture of concern. It will be the responsibility of the registrant to contact the supplier or manufacturer of the proprietary ingredient or mixture to determine the identity of the formulant(s) of toxicological concern present in the pest control products and to take appropriate action as outlined above for each of the lists of formulants.

(b) New and Amended Products

The PMRA will notify the registrant if the proposed new or amended pest control product contains a proprietary formulant or mixture with ingredients of concern. It will be the responsibility of the registrant to contact the supplier or manufacturer of the proprietary ingredient or mixture to determine the identity of the formulant(s) of toxicological concern present in the proposed new or amended pest control product and to take appropriate action as outlined above for each of the lists of formulants.

4.11 Research Permits

Formulants in products proposed for research are subject to this policy. In the case of a new formulant, the data/information required would depend on the proposed use of the product and the potential exposure. Sufficient data/information to allow for a quantitative risk assessment may be necessary to evaluate the risks posed by the presence of a new formulant in a pest control product for which a research permit is requested.

4.12 Adjuvants Added to Pest Control Products Prior to Application (tank-mix adjuvants)

Adjuvants are formulants that are sold and used separately for in-tank mixing by the end-user. Adjuvants intended to directly improve the efficacy or enhance the biological performance of a pest control product by modifying or enhancing physical or chemical characteristics are subject to the Pest Control Products Regulations as outlined in Regulatory Directive DIR93-15, *Registration Requirements for Adjuvant Products*.

While such adjuvants are subject to the data requirements described in DIR93-15, all the individual ingredients of these adjuvants are also subject to the conditions laid out in this policy.

4.13 Labelling Requirements for Formulation Preservatives

Certain registered end-use product formulations contain pesticidal active ingredients previously described as formulants. These active ingredients are generally included in a formulation in small amounts to protect the formulation from being denatured or degraded by pests. Examples include the addition of an insecticide at 0.1% to a rodenticide bait to prevent feeding by insects and the addition of formaldehyde to aqueous formulations to prevent bacterial growth. The past practice has been to consider such active ingredients as formulants and to not list them in the guarantee statements of product labels. Examples of formulation preservatives that are active pesticidal ingredients include, **but are not limited to**, formaldehyde, paraformaldehyde, malathion, chloropicrin and glutaraldehyde.

Any active ingredient whose function is to preserve or protect the formulation is to be so specified on the SPSF and on the product label with the following statement:

> "Contains (*insert name of active ingredient*) at (*insert percent weight/ weight*) % as a preservative."

This statement must be placed on the label in proximity to, on the same panel as, and in a type and font size comparable to, the guarantee statement.

If the preservative is an active ingredient that is registered in Canada, only a registered source may be used.

Registrants of formulations containing preservative ingredients were required to disclose preservatives on product labels by 9 July 2005. Label disclosure may be carried out through notification. After 9 July 2005, SPSF revisions and submission of letters of confirmation of source of supply from the supplier/registrant of the preservative where the preservative is a registered product will be done through the next amendment application or registration renewal (beginning with renewal 2006, i.e., products expiring 31 December 2006), whichever comes first.

As of 9 July 2005, applications for new products containing formulation preservatives or product amendments involving the addition of formulation preservatives are subject to the same labelling requirements described above as a requirement for obtaining registration/amended registration.

4.14 Labelling Requirements for Formulants That Are Allergens Known to Cause Anaphylactic Type Reactions

Registrants of products containing the following common allergenic substances known to cause anaphylactic type reactions as formulants must amend their product labels to add the following statement:

> "Warning, contains the allergen (*insert name of allergen*)."

Milk; eggs; fish, crustaceans, shellfish; peanuts, soy, tree nuts or their shells; sesame seeds; wheat; and any protein-containing derivative of these substances (including hydrolyzed plant protein, starch and lecithin); and sulphites.[9]

This statement must be placed on the label in proximity to, on the same panel as, and in a type and font size comparable to, the guarantee statement.

Products containing the above allergenic formulants must be labelled with this statement by 9 July 2005. Label disclosure changes may be carried out by notification and will apply to all product labels. Labels may be printed to show this statement or may be overstickered.

As of 9 July 2005, applications for new products containing allergenic formulants or product amendments involving the addition of allergenic formulants received after the effective implementation period for the Formulants Policy will be subject to the same labelling requirements described above as a requirement for obtaining registration/amended registration.

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9 Zarkadas, M. et al. 1999. Common Allergenic Foods and Their Labelling in Canada: A Review. *Canadian Journal of Allergy and Clinical Immunology*, Vol. 4, No. 3, 1999.

4.15 Acceptability Criteria for Dyes and Colourants, Fragrances or Oils Used as Formulants

(a) Dyes and Colourants

To be permitted for use in pesticide products, colourants or colourant ingredients must be on the PMRA or USEPA List 3 or 4, have been determined to be acceptable to the PMRA for use as a colourant, have been approved in Canada for food or drug use (Section 16, *Food and Drugs Act*) or have an appropriate USEPA exemption from the requirements of a tolerance in which case, the pesticide product containing the colourant must also meet the conditions associated with the exemption.

Registrants of pest control products are required to replace colourants that do not meet these criteria with acceptable colourants by 31 December 2007.

Where the total percentage of the substituted colourant does not exceed 1% by weight of the formulation, the product is not intended for use on or mixing with seeds and is not an antifouling paint, the PMRA should be advised of the substitution by notification. If the total percentage of the substituted colourant exceeds 1%, or the product is intended for use on or mixing with seeds or is an antifouling paint, the registrant must submit an application for amendment. Colourants in excess of 1% of the formulation may be subject to data review.

(b) Fragrances

Only fragrances or fragrance ingredients listed on the PMRA or USEPA List 3 or 4, or that have been determined to be acceptable to PMRA, or that are approved in Canada for food or drug use, as appropriate, may be used as formulants. Each component of a fragrance that is not on the PMRA or USEPA List 3 or 4, has not been determined to be acceptable to the PMRA or has not been approved for food and drug use, and is present at greater concentration than 0.1%, may be subject to review. If a fragrance has identified toxicological concerns, it may be subject to data requirements and risk assessment. The total amount of fragrance may not exceed 1% by weight of the formulation.

Registrants are required to replace fragrances that do not meet the acceptability criteria described above and are currently used in pest control products with acceptable fragrances by 31 December 2007. Where the total percentage of the substituted fragrance does not exceed 1% by weight of the formulation, the PMRA may be advised of this substitution by notification. If the total percentage of the substituted fragrance exceeds 1%, the registrant must submit an application for amendment.

(c) Mineral Oils

To be considered a List 4A formulant, a mineral oil must meet the United States Pharmacopoeia requirements for purity (Class 5, USFDA; Food Chemical Codex [*Codex Alimentarius*]), or equivalent. An oil not meeting these criteria will not be considered to be a List 4A formulant and will be subject to the requirements of the list to which it is categorized.

4.16 Changes Concerning Formulants Allowable by Notification

Changes to a label or a formulation of a control product generally require an application for amended registration and necessary supporting documentation and data. However, certain changes to products may be done through notification. When changes are made by notification, labels and SPSFs should not be submitted. Specific changes to labels and formulations are outlined in this Regulatory Directive. They will be allowable by notification if they meet the following criteria.

(a) Disclosure Labelling for a Formulation Containing a List 1 Formulant Where:

- a letter of notification is received prior to the specified deadline, which will be established by the PMRA (refer to Part I, Section 4.3 of this Regulatory Directive);
- the registrant commits, in the letter of notification, to remove the List 1 formulant or to provide the data to support the continued use of the List 1 formulant by the specified deadline date; and
- the registrant attests that the following statement has been added to the label and appears in proximity to, on the same panel as, and in a type and font size comparable to, the guarantee statement:

  "This product contains the toxic formulant (*insert name of chemical*) at (*insert proportion by weight*) %."

(b) Labelling for a Formulation Containing Ozone-depleting Formulants Governed by the Montreal Protocol (except TCE) Where:

- the registrant commits in the letter of notification to submit an application within the specified timeline to remove the ozone-depleting formulant from the formulation; and

- the registrant attests that the following statement has been added to the label and appears prominently on the primary panel:

  "WARNING: This product contains (*insert name of chemical*), which harms public health and the environment by destroying the ozone in the upper atmosphere."

(c) Labelling for Control Products Containing Common Allergens Where:

- a letter of notification was received by 9 July 2005; and
- the registrant attests that the following statement has been added to the label and appears in proximity to, on the same panel as, and in a type and font size comparable to, the guarantee statement:

  "Warning, contains the allergen (*insert name of allergen*)."

(d) Addition, Deletion or Substitution of Colourants Where:

- the total percentage of changed, new, added or deleted colourant does not exceed 1% by weight of the formulation;
- the product is not intended for use on or mixing with seeds and is not an antifouling paint;
- the ingredient(s) of the colourant are on the PMRA or USEPA List 3 or 4, have been determined to be acceptable to the PMRA for use as a colourant, meet the requirements for food or drug use (Section 4.15) as appropriate or have an appropriate USEPA exemption from the requirements of a tolerance, in which case the pesticide product containing the colourant must also meet the conditions associated with the exemption; and
- the product is not a technical grade of active ingredient.

(e) Addition, Deletion or Substitution of One or More Fragrances Where:

- the total percentage of the changed, added or deleted fragrance does not exceed 1% by weight of the formulation;
- the composition of the fragrance has been provided to the PMRA by the supplier or manufacturer, or registrant;

- the ingredient(s) of the fragrance are on the PMRA or USEPA List 3 or 4 or the fragrance has been determined to be acceptable to the PMRA at the proposed concentration or the ingredient(s) of the fragrance meet the requirements for food or drug use as appropriate; and

- the product is not a technical grade of active ingredient.

(f) Change in Nominal Concentration of Formulant Where:

- the nominal concentration falls within the certified limits for that ingredient as listed on the accepted SPSF;

- the composition of the formulant is known to the PMRA;

- the formulant is not on the PMRA or USEPA List 1; and

- the formulant does not contain contaminants of toxicologic concern.

(g) Change in Certified Limits of Formulant Where:

- the certified limits fall within standard certified limits;

- the PMRA has not previously determined that alternative or special certified limits apply; and

- the nominal concentration has not previously been changed by notification (see item (f) above).

(h) Change in Formulation Process Where:

- only a blending or dilution of product components is involved;

- the nominal concentration and certified limits of the active ingredient(s) and formulants do not change; and

- the physical, chemical and biological characteristics or the performance of the product remain unchanged.

NOTE: An application for amended registration is required when changes in the formulation process involve a chemical reaction.

(i) **Change of Supplier of a Formulant Where:**

- the composition of the formulant is known to the PMRA;
- the CAS registry numbers are the same;
- the formulant is not on the PMRA or USEPA List 1;
- the formulant does not contain contaminants of toxicologic concern; and
- the formulant is not proprietary.

5.0 Regulatory Actions for New Formulants in Canadian Pest Control Products

Any formulant proposed for use in a pest control product is considered to be "new" if it is not currently identified as being present in a registered Canadian pest control product or on the USEPA lists. The requirements for new formulants are under consideration. The requirements listed in the Regulatory Proposal PRO2000-04, which at the time the proposal was released were harmonized with the USEPA, are no longer harmonized. The USEPA released a document entitled *Methodology for Lower Toxicity Pesticide Chemicals; Notice of Availability*, which describes their new method and data requirements for evaluating inert ingredients. It is the PMRA's intention to harmonize as much as possible with the USEPA's new approach, and the PMRA will be releasing a regulatory proposal on new formulant requirements, for comment. In the meantime, applicants should contact the PMRA for guidance if they wish to propose a new formulant for use in pest control products.

PART II Guidance on How to Comply with the Formulants Policy

1.0 Introduction

This part of the document provides practical guidance to applicants/registrants on the implementation of the Formulants Policy. Included are descriptions of the major changes to the regulation of formulants in Canada and how these will affect currently registered pest control products as well as applications submitted to register, to amend or to renew registrations or to conduct research with pest control products. Guidance on the processes for complying with the new requirements and related regulatory action is also provided.

2.0 PMRA List of Formulants

The PMRA List of Formulants contains all formulants found in currently registered Canadian pest control products. This list is published as a regulatory note and is also available on the PMRA website. As of the date of publication of this policy, the current version is REG2005-01. This list provides a guidance tool for industry in the selection of formulants and will be updated regularly and published under a new version number. Revisions to the list may result from the following:

- New formulants will be added to the list.
- Formulants will be deleted from the list when they are no longer found in registered pest control products.
- A formulant may be reclassified as the result of new information on the formulant or as the result of formulant reassessment.

The list has been sorted in two ways, by CAS number and by list categorization number (i.e., List 1, List 2, List 3, List 4A, List 4B). The list includes the formulant names, their associated CAS number and their corresponding list categorization numbers. Allergens requiring disclosure labelling are flagged on the list. The sorted lists are ordered numerically by CAS number, and where no CAS number exists, that portion of the list is ordered alphabetically according to the formulant name. The same naming convention for formulants (inert/other ingredients) used by the USEPA for their List of Inert Ingredients has been used for the PMRA List of Formulants.

Applicants/registrants should also refer to the USEPA List of Inert Ingredients (available on the Internet at www.epa.gov/opprd001/inerts/lists.html) for additional formulants that may be acceptable (i.e., List 3, 4A, 4B), with some exceptions, for use in pest control product formulations without the requirement for additional data/information on the formulants alone. Where the list category number assigned to a particular formulant in Canada differs from that assigned by the USEPA, regulatory action, as outlined in Part I of this document, is based on the PMRA list category number.

3.0 Formulant Reclassification

Formulants may at any time be reclassified by the PMRA to another list category number (e.g., List 2 formulant reclassified to List 1) based on new information/data or as a result of reassessment. When a formulant is reclassified to another list category number, any product containing that formulant is subject to the regulatory action prescribed for that list category number. When a formulant is proposed for reclassification to List 1, registrants will be advised and given an opportunity to comment through a regulatory proposal document.

4.0 Implementation Approach

The Formulants Policy Regulatory Directive contains new requirements and requirements that are already in effect. New requirements prescribed in the Formulants Policy Regulatory Directive are being phased-in over three years, with the first requirement effective 9 January 2005. The phased implementation is designed to minimize the immediate impact on registrants/applicants and the PMRA as well as to allow adequate preparation time. The new requirements, implementation deadlines and impact on registered products and applications are described in the following sections and summarized in Appendix II. Compliance with these requirements is a condition of registration.

4.1 Labelling Disclosure Deadlines for Allergens and Formulation Preservatives

The implementation deadline date (9 July 2005), listed in this Regulatory Directive for disclosure labelling of allergens and formulation preservatives, applies to the label text version of the product label. Registrants of products containing allergens and/or formulation preservatives were required to take action to amend the label text version of the product labels by 9 July 2005, using the options described in this Regulatory Directive. A four-month grace period will be given to registrants before the PMRA considers taking any action for failure to meet this deadline. In order to provide registrants with additional time to prepare for marketplace label implementation, pest control product containers labelled after **9 July 2006**, i.e., 12 months after the implementation deadline date, are required to have the appropriate disclosure statements on the marketplace labels.

5.0 Requirements Already in Effect

As per current practice, the following requirements are already in effect and will continue to be required.

5.1 Formulant Information

When a formulant is unknown to the PMRA, the following information must be provided to support an application to register, to amend, to renew or to conduct research with pest control products:

- An updated material safety data sheet (MSDS) for the formulant.
- If the MSDS does not disclose all of the components of the formulant (in the case where the formulant is a mixture), then a confidential statement of ingredients, including chemical names, CAS number and percentage composition of each component of the formulant is also required.

It is understood that a pesticide formulator or registrant is not necessarily privy to the proprietary information on the components of a mixture; therefore, an applicant can request the supplier/manufacturer of the formulant to send this information directly to the PMRA. Please ensure that when formulant information is submitted, the submission number is referenced. This information will be held in confidence by the PMRA and will be used only by the screening and reviewing sections when assessing pesticide submissions or during the re-evaluation of formulated end-use products.

Failure to submit the required formulant information with an application to register, to amend, to renew or to conduct research with a pest control product will be treated as a screening deficiency. The review of the submission cannot be completed in the absence of the required formulant information. As a result, if the required information is not provided within the deficiency response time, the submission will be rejected. A new application may be made when the formulant information becomes available.

If the information is provided within the required time frame and it allows the PMRA to determine the formulant's acceptability, processing of the application will continue.

If the formulant or the component of a formulant (where the formulant is a mixture) is determined to be new to the PMRA and USEPA, information will be required in order to assess the acceptability of the formulant.

5.2 New Formulants

Any formulant proposed for use in a pest control product is considered to be "new" if it is not currently identified as being present in a registered Canadian pest control product or on the USEPA lists of inert ingredients. The data/information requirements for new formulants are under consideration. It is the PMRA's intention to harmonize as much as possible with the USEPA's new approach for assessing inert ingredients as outlined in their document *Methodology for Lower Toxicity Pesticide Chemicals*. The PMRA will soon be releasing a regulatory proposal on the requirements for new formulants. In the meantime, applicants should contact the PMRA for guidance if they wish to propose a

new formulant for use in pest control products. In general, the PMRA will require sufficient data/information to assess the potential risk of the formulant. Initially applicants will be asked to submit available information (e.g., information obtained through a literature search) to address potential areas of concern.

5.3 List 1 Formulant Label Disclosure

As of the date of publication, the only registered products still containing List 1 formulants are those for which an application has been made to replace the List 1 formulant or to support the continued use of the List 1 formulant in that product.

These products containing List 1 formulants are currently subject to label disclosure of the identity and amount of the List 1 formulant contained in the product. The following statement must appear on the labels for those products containing a List 1 formulant:

> "This product contains the toxic formulant (*insert name of chemical*) at (*insert percent weight/weight*) %."

This statement must be placed in close proximity to, on the same panel as, and in a type and font size comparable to, the guarantee statement.

6.0 New Requirements

The following are new requirements arising from the Regulatory Directive DIR2004-01, *Formulants Program*.

6.1 Statement of Product Specification Forms (SPSFs)

As of 9 January 2005, all applications submitted to register, to amend, to renew or to conduct research with, a pest control product must be accompanied by a SPSF. Exceptions to this requirement are applications for private label products and devices where a SPSF is not required. Please note the following when completing SPSFs:

- Where a product has more than one formulation under the same registration number, all formulations must be included when SPSFs are submitted.
- Where a technical grade active ingredient has more than one site of manufacture under the same registration number, each site must be represented on a separate SPSF.
- To ensure that the SPSF is completed correctly, read the instructions for completing the SPSF, including the examples provided with the form. Also, refer to Appendix 1 for a list of common errors made by applicants when completing SPSFs.

Applications **received before 9 January 2005**, for which a SPSF was not required at the time of filing (e.g., label amendment only), will be processed without a SPSF.

NOTE: It is the registrant's responsibility to ensure that the SPSF on file with the PMRA is current, i.e., the registrant must document SPSF modifications either through submission of an application for product amendment or through notification where allowed. Modifications that require an application include, but are not limited, to the following:

- changing or adding formulants where the new formulants are different from those currently listed on the SPSF on file;
- changing the proportions of formulants and/ or the product(s) that provides the active ingredient(s);
- adding/changing a site of manufacture for a technical grade active ingredient; and
- changing the product(s) that provides the active ingredient(s) in the formulation of an end-use product or manufacturing concentrate.

To determine which modifications are allowable through notification refer to Section 4.16 of Part I of this document.

6.2 List 2 Formulants

6.2.1 Reclassification of List 2 Formulants

As indicated in Part I of this document, all List 2 formulants will be scheduled for reassessment. Should the reassessment, or an evaluation of data submitted with an application to support the continued use of a List 2 formulant, determine that the formulant does not pose an unacceptable level of risk to human health and the environment under the specific conditions of use, the formulant will be reclassified to List 4B. Should the data provided indicate an unacceptable risk, the List 2 formulant will be reclassified to List 1, and the product will be subject to the appropriate List 1 regulatory action as outlined in this Regulatory Directive. If the data submitted are insufficient to perform a risk assessment, registrants will be so advised and provided with options for dealing with the formulant. Options will include discontinuation of products containing the formulant, replacement/removal of the formulant and submission of data to allow for a complete risk assessment of the formulant under specific conditions of use.

6.3 Formulation Preservatives

A formulation preservative added to a pest control product to protect the formulation from degradation or denaturation by pests is itself by definition a pest control product active ingredient under the PCPA. Since formulation preservatives are by definition active ingredients, they will no longer be described as formulants.

Formulation preservatives do not contribute to the intended effect of the control product to which they are added. For example, insecticides added to rodenticide baits to prevent feeding by insects are considered formulation preservatives, and antimicrobial and antifungal agents added in small amounts to pesticide formulations to prevent bacterial and fungal growth within the container are also considered formulation preservatives.

Formulation preservatives are added to pest control products either directly as a single ingredient or by way of a formulated product that itself contains formulants in addition to the formulation preservative active ingredient. Formulation preservative labelling requirements pertain to the formulation preservative active ingredient(s). Where the formulation preservative itself is a formulated product, both the formulation preservative product and its active ingredient(s) must be declared on the SPSF. For example, in the case of XYZ Preservative, both XYZ Preservative and its active ingredient, e.g., formaldehyde, would be listed on the SPSF.

Please note that substances used in pest control product formulations whose function does not make them active ingredients according to the PCPA definition (e.g., antioxidants), would not be subject to formulation preservative requirements as described in this Regulatory Directive regardless of whether they are regulated under the Canadian *Food and Drugs Act* as food additive preservatives. They would be classified as formulants and not formulation preservatives. For example, in the case of antioxidants their purpose in the formulation would be listed on the SPSF as "antioxidant". In other words, only substances whose function makes them active ingredients according to the PCPA definition (e.g., mould inhibitors) would be subject to the formulation preservative requirements and disclosed on the SPSF as "formulation preservatives".

6.3.1 Formulation Preservative Disclosure on the SPSF and Label

Any formulation preservative active ingredient as described above must be identified as a formulation preservative on the SPSF under purpose in the formulation and on the pest control product label. The following statement must be placed on the label in proximity to, on the same panel as, and in a type and font size comparable to, the guarantee statement:

> "Contains (*insert name of formulation preservative active ingredient*) at (*insert percent weight/weight*) % as a preservative."

This labelling requirement applies to all formulation preservatives used in pest control products including those containing active ingredients that are registered and those containing formulation preservative active ingredients that are not registered. Please note that it is the name of the formulation preservative active ingredient (common or chemical) and not the tradename of the preservative product that is to appear in the disclosure statement.

An exception to the preservative labelling requirement is being made for microbial products. For these products, label identification of the formulation preservative(s) will not be required. The addition of formulation preservatives, often a complex system of multiple preservatives, is critical to protecting the viability of the active ingredient (microorganism) itself rather than to preserving the formulation.

6.3.2 Label and SPSF Amendment Submission Timelines

Products (containing formulation preservatives) Registered Before 9 July 2005
The Formulants Program Regulatory Directive (DIR2004-01) indicated that registrants of products containing formulation preservatives were required to submit applications to amend product labels and SPSFs as well as to provide letters of confirmation of source of supply (LOCs) by 9 July 2005 to address the formulation preservative requirements. In order to reduce the burden associated with this approach to addressing the preservative requirements, registrants may instead choose to address the formulation preservative requirements in two phases as outlined in the following:

Phase 1—Label Disclosure
In the first phase, formulation preservative active ingredients must be disclosed on product labels (label text version). Label disclosure may be documented through notification, and the letter of notification must have been submitted by 9 July 2005. The letter must include the exact statement that is being added to the label text as well as specifying the location of the statement as it will appear on the marketplace label.

Where the formulation preservative(s) has been added to a pest control product (e.g., XYZ Insecticide) by way of a formulated product (e.g., ABC Microbiocide), the name and guarantee of the formulation preservative active ingredient must be listed on the label of the pest control product (XYZ Insecticide). The identity and concentrations of the formulants found in the preservative product (ABC Microbiocide) are not to be disclosed on the label for XYZ Insecticide. In the case of ABC Microbiocide, the active ingredients, e.g., 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one, as well as their guarantees in XYZ Insecticide would be listed on the XYZ Insecticide label.

Phase 2—SPSF Disclosure
In the second phase, revision of SPSFs, if necessary, and submission of letters of confirmation of source of supply, where applicable, will be done after 9 July 2005 through the next amendment application or at registration renewal (beginning with

Renewal 2006, i.e., products expiring 31 December 2006), whichever comes first. A revised SPSF is required if the formulation preservative active ingredient is not currently disclosed on the SPSF as a formulation preservative and/or the guarantee of the preservative active ingredient is not disclosed appropriately.

Where the formulation preservative(s) has been added to a pest control product (e.g., XYZ Insecticide) by way of a formulated product (e.g., ABC Microbiocide), the name and guarantee of the formulation preservative active ingredient(s) must be listed on the SPSF for the pest control product (XYZ Insecticide) in addition to the name and amount (%w/w) of the formulation preservative product (ABC Microbiocide). The guarantee of the formulation preservative should be expressed in terms of nominal or minimum concentration as appropriate. The identity and concentrations of the formulants found in the preservative product (ABC Microbiocide) are not to be disclosed on the SPSF for XYZ Insecticide. In the case of ABC Microbiocide, the active ingredients, 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one, and their guarantees in XYZ Insecticide would be listed on the SPSF for XYZ Insecticide. ABC Microbiocide and its %w/w in the pest control product would also be listed on the SPSF for XYZ Insecticide.

A Letter of Confirmation of Source of Supply from the supplier/registrant of the formulation preservative must be included with the application when the formulation preservative is registered in Canada as a pest control product. This applies to cases where the formulation preservative is added directly as a single ingredient that is registered (e.g., malathion; Reg. No. XXXX) and where it is added by way of a formulated product that is registered (e.g., ABC Microbiocide; Reg. No. YYYY).

Applications Received Before 9 July 2005

Applications received before 9 July 2005 for which the certificate of registration/amended registration is issued after this date will require label disclosure, i.e., the preservative statement must be on the approved text label before the certificate is issued. Revised SPSFs and LOCs will not be required to be submitted in order to complete registration. However, if applicants wish to use such applications to incorporate all formulation preservative requirements, they should first contact the Pest Management Information Service.

Applications Received After 9 July 2005

All applications to register products containing formulation preservatives and amendments involving the addition of formulation preservatives, received after 9 July 2005 must comply with the formulation preservative requirements.

Registration Renewal—SPSF Amendments Involving Identification of Formulation Preservatives

Amendments to the SPSF, which involve only identification of formulation preservatives already contained in pest control products and/or the submission of LOCs for registered formulation preservative products, will be accepted as part of the renewal process as noted in the section describing Phase 2 above.

6.3.3 Registration of Preservatives

In general, formulation preservatives used to control, prevent, destroy or mitigate a pest, as defined in the PCPA, are subject to registration under the PCPA. Consideration will be given to waiving the requirement for registration of preservatives that are already regulated as food additives under the Canadian *Food and Drugs Act* where the levels of exposure from pest control products are consistent with the levels of exposure as food additives. Many formulation preservatives are already registered in Canada. If the formulation preservative is already registered in Canada as an active ingredient, only a registered source may be used for preservation purposes in a pesticide formulation. Registrants currently using unregistered sources of formulation preservatives must apply to substitute with a registered source or register the source of the formulation preservative by 9 January 2008.

Within five years of the date of this Regulatory Directive, registrants of pest control products containing formulation preservatives that are not registered in Canada (i.e., the formulation preservative or formulated product providing the formulation preservative active ingredient is not currently registered) and have not been exempted from registration must submit the following:

- an application to register these formulation preservatives (technical grade active ingredient and end-use product) for this express purpose;
- an amendment application to remove these formulation preservatives from the product formulation, (this type of amendment may be subject to an efficacy review); or
- an amendment application to replace the unregistered formulation preservative with one that is registered in Canada or with one that has been given an exemption from the requirement for registration (this type of amendment may be subject to an efficacy review).

6.4 Allergens

6.4.1 Allergen Label Disclosure

The Formulants Policy requires that labels of products containing formulants that are common allergenic substances known to cause anaphylactic type reactions, (i.e., milk, eggs, fish, crustaceans [naming the crustacean], shellfish [naming the shellfish], peanuts, soy, tree nuts [naming the tree nut] or their shells, sesame seeds, wheat, or any protein-containing derivative of these substances [including hydrolyzed plant protein, starch and lecithin] and sulphites) carry the following statement:

> "Warning, contains the allergen (*insert name of allergen*)."

This statement must be placed in proximity to, on the same label panel as, and in a type and font size comparable to, the guarantee statement.

Allergens found in currently registered pest control products are flagged on the PMRA List of Formulants. When the allergenic formulant is a derivative, it is acceptable to include only the name of the allergen source (e.g., in the case of soya lecithin, it would be sufficient to indicate "contains the allergen soy" on the product label). If the derivative's name does not indicate the allergen source and a registrant wishes to disclose the derivative, the allergen source must also be included in brackets after the name of the derivative (e.g., "contains the allergen casein (milk)").

6.4.2 Label Amendment Submission Timelines

Products Registered Before 9 July 2005
By 9 July 2005, the label text version of the product label for all registered products containing allergens must have been revised to include the required disclosure statement. Addition of this label statement must be documented via the following ways:

- the notification process, i.e., through the submission of a letter in which the registrant attests that the statement provided above has been added to the label text as required. The letter of notification must have been submitted by 9 July 2005 and must identify the exact statement that has been added and specify the location of the statement that will be on the marketplace label; or

- an application to amend or renew the registration where the submission was being completed before 9 July 2005. In this case, the registrant may opt to include the statement at the final stage of the registration process.

Applications Received Before 9 July 2005
Applications received before 9 July 2005 for which the certificate of registration/amended registration is issued after this date will require label disclosure, i.e., the allergen statement must be on the approved text label before the certificate is issued.

Applications Received After 9 July 2005
All applications to register products containing allergens or amendments involving the addition of allergens received after 9 July 2005 must comply with the allergen label disclosure requirement.

6.5 Dyes and Fragrances

As indicated in Part I of this document, the acceptability criteria for dyes used in pesticide products are the following:

- is on the PMRA or USEPA List 3 or 4;
- has an appropriate USEPA exemption from the requirements of a tolerance, and the pesticide product containing the dye meets the conditions associated with the exemption;
- is approved in Canada for food or drug use; or
- has been determined to be acceptable to the PMRA for use as a dye.

Fragrances or fragrance ingredients to be used in pesticide products must meet the following criteria:

- be on the PMRA or USEPA List 3 or 4;
- be approved in Canada for food or drug use; or
- have been determined to be acceptable to the PMRA.

By 31 December 2007, dyes and fragrances contained in pest control products that do not meet the criteria for acceptability must be replaced by acceptable dyes and fragrances.

Products Containing Dyes and Fragrances Registered Before 31 December 2007
By 31 December 2007, the appropriate documentation must have been received by the PMRA to address the acceptability requirement through these two means:

1. **notification** where:

   - the amount of the dye/fragrance in a formulation does not exceed 1% w/w; and

   - for the case of a dye, the product containing the dye is not intended for use on or mixing with seeds and is not an antifouling paint.

2. **an application for product amendment** where:

   - the amount of the dye/fragrance is greater than 1% w/w; and/or

   - for the case of a dye, the product containing the dye is intended for use on or mixing with seeds, or is an antifouling paint.

Applications Received Before 31 December 2007

Amendment applications completed before **31 December 2007** for which the purpose is to make an amendment other than those required under this Section will not be required to replace dyes and fragrances that do not meet the criteria for acceptability in order to obtain the certificate of registration. However, if applicants wish to use such applications to incorporate the required dye/fragrance changes, they should first contact the Pest Management Information Service.

Applications to register new products for which the certificate of registration is issued after **31 December 2007** will not be required to replace dyes and fragrances which do not meet the criteria for acceptability in order to obtain the certificate of registration. However, if applicants wish to use such applications to incorporate the required dye/fragrance changes, they should first contact the Pest Management Information Service.

If the dye/fragrance requirements are not addressed through the new product application, an application to amend the product registration or letter of notification if applicable to comply with the dye/fragrance requirements must be submitted within 90 days of the initial registration.

NOTE: Although applications received before **31 December 2007** are not required to comply with the criteria for acceptability, fragrances containing List 1 formulants will not be considered for use in pest control products unless data are submitted to support the use of the List 1 formulant. In addition, fragrance components that are not known to the PMRA and are present at significant levels (i.e., greater than 0.1%) may be subject to a requirement for data.

Applications Received After 31 December 2007
All applications to register products containing dyes or fragrances received after **31 December 2007** must comply with the dye/fragrance acceptability criteria requirements.

6.6 Multiple Formulations Under the Same Registration Number

Multiple formulations are defined as more than one formulation acceptable under the same registration number when the formulations differ with respect to the proportions and/or identity and composition of formulation ingredients. Certain types of multiple formulations can be represented on the same SPSF, while others must be represented on separate SPSFs, as outlined in Section 6.6.2.

NOTE: The use of alternate products providing the active ingredient that have the same guarantee and contain the same formulants in the same concentrations are not included in the definition of multiple formulations.

6.6.1 Acceptability Criteria

More than one formulation under the same registration number is allowed, provided the PMRA assesses each formulation and determines that:

- the product chemistry is substantially similar, i.e., only minor differences in the physical and chemical characteristics;
- with respect to toxicology, the formulations have the same hazard classification used for labelling purposes (data may be required to support this);
- the formulations have the same performance as claimed on the label (data may be required to support this);
- the registrant provides a mechanism for identifying the formulation found within a particular container. Examples of this would include the following:
    - batch or lot number, and
    - colour listed on the label if the products are antifouling paints or pet collars and the formulations differ only in the dye.

6.6.2 How to Represent Multiple Formulations on the SPSF

Formulations That Should Be Represented on the Same SPSF
The following type of multiple formulations should be represented on the same SPSF. These involve the use of alternate ingredients in the same amount such that the amounts of the other ingredients in the formulation are not affected.

The formulations involve the use of alternate formulants as described above in the same amount (%w/w), e.g., in Formulation 1, Formulant A is used at X%; in Formulation 2, Formulant A has been replaced with Formulant B at the same amount (X%).

Formulations That must Be Listed on Separate SPSFs
The following types of multiple formulations must be listed on separate SPSFs as they involve the use of alternate ingredients in a manner that affects the proportions of other ingredients.

- The use of different products that provide the active ingredient that have different guarantees (different amounts of these products would need to be used in order to obtain the same guarantee for the formulated product.)

- The use of different formulants where the amounts of the formulants are not the same (e.g., Formulant A is used in Formulation 1 at 5% w/w; in Formulation 2, it is replaced with Formulant B at 7% w/w. This would also involve an adjustment in the concentration of another formulant(s) in order to ensure a total w/w of 100%).

Identification of SPSFs

In order to simplify and standardize the identification and tracking of multiple formulations under one registration number, the assignment of a unique identifier corresponding to each formulation will replace the current system of "basic" and "alternate" designations.

When a product with multiple formulations requiring separate SPSFs is registered, each SPSF must be identified with a different formulation number and a version number that are assigned sequentially, beginning with 1, i.e., Formulation 1, Version 1; Formulation 2, Version 1; Formulation 3, Version 1; and so forth. Each time a formulation is revised through an amendment application, a new version number is assigned. (A new version number is not required when only notifiable changes are made to a SPSF.) For example, if Formulation 2, Version 1 is amended or replaced, it would become Formulation 2, Version 2. The addition of a new formulation would result in a new formulation number, e.g., Formulation 4, Version 1.

Some examples of SPSF numbering are as follows:

A registrant currently has a product registered with three formulations, each represented on its own SPSF, i.e., Formulation 1, Version 1; Formulation 2, Version 1; Formulation 3, Version 1.

1. The registrant wishes to amend the second formulation (Formulation 2, Version1). This amended version becomes Formulation 2, Version 2.

2. The registrant wishes to add another formulation while maintaining the three current formulations. The new formulation would be Formulation 4, Version 1.

3. The registrant wishes to replace the third formulation (Formulation 3, Version 1) with a different formulation. The replacement formulation would be Formulation 3, Version 2; Formulation 3, Version 1 would become historical.

NOTE: Based on this numbering system, there can never be more than one current formulation with the same formulation number. For example, a registrant could not have Formulation 1, Version 1 and Formulation 1, Version 2 as current formulations because once a formulation is revised, the previous version is no longer current. (If a registrant wanted to retain Formulation 1, Version 1 and also introduce a revised version, the revised version would be assigned a new number, e.g., Formulation 4, Version 1.)

The SPSF has been revised to facilitate the use of the new numbering system. Therefore, applicants/registrants should start using the new numbering system as soon as possible, i.e., for the next application submitted to the PMRA to register, to amend, to renew or to conduct research with a pest control product.

6.6.3 Label Disclosure for Products with Multiple Formulations

When a product is registered with multiple formulations that have differing label disclosure requirements, all formulants subject to disclosure as well as formulation preservatives will be required to be declared on the label text version of the label. However, the marketplace labels must only disclose the formulant(s) or formulation preservative(s) found in the particular formulation being labelled for sale in the marketplace. An example would be as follows: A registered product has two formulations. Formulation 1 contains an allergen (wheat) that is required to be disclosed on the product label. Formulation 2 does not contain wheat; however, it does contain a formulation preservative (formaldehyde). On the label text version of the product label, both wheat and formaldehyde would be disclosed. The marketplace label for Formulation 1 would contain only the disclosure statement for wheat and not for formaldehyde. Similarly, the marketplace label for Formulation 2 would contain only the disclosure statement for formaldehyde and not for wheat.

6.6.4 Registered Products Containing Multiple Formulations

Multiple formulations not meeting the criteria described above will not be allowed under the same registration number; therefore, they would have to be registered under separate registration numbers through a Category C application. **Beginning six months from the date of publication of this Regulatory Directive**, all applications to register new pest control products or to add formulations to registered products will be subject to the acceptability criteria described in Section 6.6.1. (In the case of addition of new formulations to registered products, the new formulations must comply with the acceptability criteria.) Time frames and processes for handling currently registered products that contain multiple formulations not meeting the acceptability criteria will be developed.

In the interim, in order to comply with these requirements, registrants may delete one or more formulations of a currently registered product through renewal or through an amendment application.

7.0 Notifiable Changes

Changes to a label or a formulation of a control product generally require an application for amended registration and necessary supporting documentation and data. However, certain changes to labels and formulations as specified in this Regulatory Directive may be accommodated via the notification process, if they meet the prescribed criteria. (Refer to Part I, Section 4.16) Please note that when notifying the PMRA of these changes, a label or SPSF should not be submitted. A letter attesting to the specific changes made is all that is required.

For notifiable changes involving the addition, deletion or substitution of colourants or fragrances, or change in nominal concentration of a formulant, which result in changes in the amounts of other formulants in a product formulation, a description of these changes (including formulant name and amount) must also be included in the letter of notification. The amounts of formulants subject to disclosure labelling cannot be changed through notification and would require an application for product amendment.

List of Abbreviations

CAS	Chemical Abstracts Service
CEPA	*Canadian Environmental Protection Act*
CFC	chlorinated fluorocarbons
DACO	data code
FR	Federal Register
HCFC	hydrochlorofluorocarbon(s)
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
LOC	letter of confirmation of source of supply
MSDS	material safety data sheet
OECD	Organisation for Economic Co-operation and Development
PCPA	*Pest Control Products Act*
PMRA	Pest Management Regulatory Agency
Q-SAR	quantitative structure activity relationship
SPSF	statement of product specifications form
TCE	1,1,1-trichloroethane
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency
USFDA	United States Food and Drug Administration

Appendix I Common Errors Made When Completing SPSF

The following common errors/omissions are often made by applicants.

- Formulation code, e.g., SN (solution) is often confused with formulation type code, e.g., IN (insecticide). Please refer to list of formulation codes provided on SPSF instruction sheet.

- All formulations (when a product has multiple formulations registered under the same registration number) are not included with applications as described in this document.

- A separate SPSF is not used for each distinct site of manufacture for a technical grade active ingredient when there is more than one site of manufacture under the same registration number.

- Multiple formulations are not clearly identified as described in this document, i.e., an identifier not included for each formulation at the top of each SPSF, e.g., Formulation 1, Version 1; Formulation 2, Version 1; etc.

- Guarantee of an end-use product is not expressed in the same manner as the product used to provide the active ingredient, i.e., if the guarantee of the product providing the active ingredient is expressed as a minimum, the end-use product guarantee should also be expressed as a minimum (with no value for N=, or the upper limit). The guarantee expression (minimum versus nominal) for registered pest control products is available on the PMRA's website using ELSE Search and selecting the More Info button.

- The guarantee of an end-use product listed on the SPSF does not equal the value calculated using the purity of the product providing the active ingredient (i.e., the amount of active ingredient found in the product providing the active ingredient) and the amount (%w/w) of this product used in the formulation. If the product is intentionally over-formulated based on the stability of the active ingredient, this should be indicated on the SPSF as a notation to the guarantee.

- Certified limits for formulants are not included, and where they exceed the standard as defined in Regulatory Directive DIR98-03, *Chemistry Requirements for the Registration of a Manufacturing Concentrate or an End-Use Product Formulated from Registered Technical Grade of Active Ingredients or Integrated System Products*, a scientific rationale to support wider limits is not provided.

- Applicants have not verified that products used to provide the active ingredient in end-use products and manufacturing concentrates are still registered, i.e., that the registration has not expired.

Appendix II Summary of Time Frames for New Requirements

Item	Requirement and Time Frame	Effect on Applications Received Prior to Implementation Date
SPSFs Part II, Section 6.1	**As of 9 January 2005,** SPSFs must be submitted with all applications to register, to amend, to renew or to conduct research with pest control products.	Refer to Section 6.1
Allergens Part II, Section 6.4	**By 9 July 2005,** allergens must be disclosed on all registered product labels (label text version) through notification or an amendment application that is completed by this date[10]. **Beginning 9 July 2005,** all applications submitted to register or to conduct research with new pest control products must comply with the allergen disclosure requirement.	Refer to Section 6.4.1
Formulation Preservatives Part II, Section 6.3	**By 9 July 2005,** formulation preservatives must be disclosed on all registered product labels (label text version) through notification or an amendment application that is completed by this date[9]. Correct disclosure of formulation preservatives on SPSFs and submission of LOCs where applicable are to be done through the next amendment application submitted after this date or at the next registration renewal (beginning with Renewal 2006, i.e., products expiring 31 December 2006), whichever comes first. **Beginning 9 July 2005,** all applications submitted to register, to amend or to conduct research with pest control products must comply with the formulation preservative disclosure requirement.	Refer to Section 6.3.1

10 Pest control products containers labelled after **9 July 2006** are required to have the appropriate allergen and formulation preservative disclosure statements on the marketplace label.

Item	Requirement and Time Frame	Effect on Applications Received Prior to Implementation Date
Multiple formulations Part II, Section 6.6	**Beginning six months from the date of this Regulatory Directive,** all applications submitted to register new pest control products or to add formulations to registered pest control products must comply with the criteria for acceptability of multiple formulations under the same registration number.	Not applicable (no effect)
Dyes Part II, Section 6.5	**As of 9 January 2004,** current practice, applications submitted to register or to amend pest control products containing dyes must comply with the criteria for acceptability. **By 31 December 2007,** dyes contained in registered pest control products that do not meet the criteria for acceptability must be replaced by acceptable dyes and documented through notification or an application for product amendment as applicable.	Refer to Section 6.5
Fragrances Part II, Section 6.5	**As of 9 January 2004,** current practice, applications submitted to register or to amend pest control products containing fragrances must comply with the criteria for acceptability. **By 31 December 2007,** fragrances contained in registered pest control products that do not meet the criteria for acceptability must be replaced by acceptable fragrances and documented through notification or an application for product amendment as applicable.	Refer to Section 6.5